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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/673,895

09/29/2003

Spencer Erich Hochstetler

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ERIC D. MIDDLEMAS
EASTMAN CHEMICAL COMPANY
P. O. BOX 511
KINGSPORT, TN 37662-5075

EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

07/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/673,895		HOCHSTETLER ET AL.	
	Examiner		Art Unit	
	Vera Afremova		1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 18-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/19/03; 5/02/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group I, claims 1-17, in the reply filed on 4/22/2007 is acknowledged. The traversal is on the ground(s) that there is no serious burden in searching and examining all groups of claims. This is not found persuasive because different groups of claims are drawn to products and methods having different scope as claimed and, thus, the references that would be applied to one group of claims would not necessarily anticipate or render obvious the other group(s). Moreover, as to the question of burden of search, classification of subject matter is also an indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Clearly different searches and issues are involved with each group. For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 18-40 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/22/2007.

Claims 1-17 are under examination in the instant office action.

Claim Rejections - 35 USC § 112

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is indefinite with respect to components during agitating step. The active step of agitating as claimed does not include neither living cells intended for disruption nor a sample suspected to comprise living cells. The differences between components that are present during agitation steps ("polymer", "pigment" and "disrupting agent") are not certain since polymer and/or pigment could be large particles and, thus, particulate agents. Moreover, claims 5 and 10 encompass the use of identical materials for both "pigment" and "disrupting agent". Thus, claim 1 appears to be uncertain and/or incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 196 25 137 (IDS reference).

Claims are directed to a method for disrupting living cells as intended for ATP release from the living cells wherein the method comprises one active step of agitating an aqueous mixture of 1) polymer or pigment in the presence of 2) a particulate disruption agent to cause rupture of the cells. Some claims are further drawn to the living cells being fungal or bacterial cells including *Candida sp.* and *Burkholderia cepacia*. Some claims are further drawn to the

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presence of a generic organic pigment during agitating step. Some claims are further drawn to the presence of polymers including polyether, acrylic polymer and/or polyesters during agitating step. Some claims are further drawn to the presence of a generic cosmetic, coating or adhesive material during agitating step. Some claims are further drawn to the presence of a generic plastic disrupting oval agent during agitating step.

DE 196 25 137 discloses a method for disrupting living cells as intended for ATP release from the living cells (see page 6, for example) wherein the method comprises active step of agitating an aqueous mixture comprising living cells and 1) acrylic polymer or a generic organic pigment and 2) a disrupting agent that is either a lysis reagent as taught by reference or a styrene polymer within the meaning of the instant claims drawn to a plastic disruption agent (claim 10). The disclosed polystyrene is in a form of dispersion and, thus, it is large enough to be considered a particulate agent having amorphous or oval shape within the meaning of the instant claims. The living cells include *Candida sp.*, *Escherichia sp.* and *Burkholderia cepacia* (page 9).

Thus, the cited patent teaches all structural elements in the method for releasing ATP from living cells as required for the claimed method. Thus, the cited reference anticipates the claimed invention.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 542 790 (IDS reference).

Claims are directed to a method for disrupting living cells as intended for ATP release from the living cells wherein the method comprises one active step of agitating an aqueous mixture of 1) polymer or pigment in the presence of 2) a particulate disruption agent to cause cell

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rupture. Some claims are further drawn to the living cells being fungal or bacterial cells including *Serratia sp.* Some claims are further drawn to the use of a generic organic pigment, to the use of a generic polyether polymer, to the use of a generic plastic disrupting round agent.

EP 542 790 discloses a method for disrupting living cells as intended for ATP release from the living cells (page 9, examples) wherein the method comprises one active step of agitating an aqueous mixture of 1) polymer in the presence of 2) a particulate disruption agent to cause cell rupture. The polymer is Triton X-100 and the particulate disruption agent is polystyrene beads (page 10, lines 1-4). The living cells belong to *Serratia sp.* (page 9, line 17).

Thus, the cited patent teaches all structural elements in the method for releasing ATP from living cells as required for the claimed method. Thus, the cited reference anticipates the claimed invention.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Calvo-Bado et al. (Applied and Environmental Microbiology. April 2003, Vol. 69, pages 2116-2125).

Claims are directed to a method for disrupting living cells as intended for ATP release from the living cells wherein the method comprises one active step of agitating an aqueous mixture of 1) polymer or pigment in the presence of 2) a particulate disruption agent to cause rupture of the cells. Some claims are further drawn to the living cells being fungal or bacterial cells including *Bacillus subtilis*, *Pseudomonas*, etc. Some claims are further drawn to the presence of a generic pigment including calcium carbonate and/or clay during agitating step. Some claims are further drawn to the presence of a generic organic polymer including cellulosic polymer during agitating step.

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Calvo-Bado et al. discloses a method for disrupting living cells as intended for ATP release from the living cells in the sand sediments for filtration of horticultural irrigation water. The disclosed method comprises active step of agitating an aqueous mixture of 1) pigment in the presence of 2) a particulate disruption agent to cause rupture of the cells. The "pigment" is sand or calcium carbonate (instant claim 5). The living cells in the sand sample are *Bacillus subtilis*, *Pseudomonas*, etc. The horticultural irrigation water filtered through the sand filter and present in the analyzed sand sample is reasonably expected to contain at least some amounts of plant residues or cellulosic polymers (instant claim 6). For example: see entire document including section "materials and methods" (page 2118).

Thus, the cited reference teaches all structural elements in the method for releasing ATP from living cells as required for the claimed method. Therefore, the cited reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 542 790 and Calvo-Bado et al. (Applied and Environmental Microbiology. April 2003, Vol. 69, pages 2116-2125) and DE 196 25 137 taken with Geciova et al ("Methods for disruption of microbial cells for potential use of the dairy industry". International Dairy Journal. 2002, 12: 541-553) and US 5,017,564.

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Claims are directed to a method for disrupting living cells as intended for ATP release from the living cells wherein the method comprises one active step of agitating an aqueous mixture of 1) polymer or pigment in the presence of 2) a particulate disruption agent to cause rupture of the cells. Some claims are further drawn to the living cells being fungal or bacterial cells including *Candida sp.*, *Serratia sp.*, *Burkholderia cepacia*, *Bacillus subtilis*, *Pseudomonas*, etc. Some claims are further drawn to the presence of a generic pigment including organic polymer, inorganic pigments, sand, etc. during agitating step. Some claims are further drawn to the presence of polymers including polyether, acrylic polymer and/or polyesters during agitating step. Some claims are further drawn to the presence of a generic cosmetic, coating or adhesive material during agitating step. Some claims are further drawn to the use of the disrupting agent made from plastic or glass, having bead shape, having diameter 0.1-1 mm. Some claims are further drawn to agitating on a bead mill with 100-10,000 oscillations per minute for 0.1-5 minutes.

The cited references EP 542 790, Calvo-Bado et al. and DE 196 25 137 teach methods for disrupting living cells as intended for ATP release from the living cells wherein the method comprise step of agitating cell samples or sample suspected in cell contaminations in an aqueous mixture of polymer or pigment in the presence of a particulate disruption agent to cause rupture of the cells and release of ATP. The references teach release of ATP and disruption of various microbial cells including *Candida sp.*, *Serratia sp.*, *Burkholderia cepacia*, *Bacillus subtilis*, *Pseudomonas*, etc. The disruption agents include plastic beads (EP 542 790), particulate plastic materials (DE 196 25 137) and glass beads (Calvo-Bado et al. page 2118, col. 1, par. 5). The aqueous mixtures of polymers and or pigments include dispersions of acrylic polymers,

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polyesters, polyethers, polystyrenes, sand sediments, clay, cellulosic plant residues from irrigation water, etc.

The cited reference by Calvo-Bado et al. also teaches the use of 0.1 mm size of beads for disruption of microbial cells as intended for ATP release and the use of BioSpect bead mill for agitation of cells with beads for about 5 minutes (page 2118, col. 1, par. 5).

Thus, the cited references EP 542 790, Calvo-Bado et al. and DE 196 25 137 as a whole teach and suggest all structural elements in the method for disrupting living cells with beads in polymer/pigment dispersions as intended for ATP release from the living cells.

The following references are additionally relied upon to demonstrate that bead size and milling time and/or speed (oscillation per minute) during disruption is commonly modified depending on type of living cells present or suspected in the samples (Geciova et al. at page 544, col. 1) and that unstable ATP could be protected in the presence of coating materials including acrylic copolymers, cellulosic polymers, colorants (US 5,017,564 at col. 6, lines 40-55).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use particulate disrupting agents including glass beads for disrupting living cells in dispersions with polymers and/or pigments with a reasonable expectation of success in releasing ATP as intended for detection of living cells as adequately taught and/or suggested by the cited references EP 542 790, Calvo-Bado et al. and DE 196 25 137. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. One of skill in the art would have been motivated to modify bead size and agitation speed with regard to the type of living cells as adequately taught and/or suggested by Geciova et al. One of skill in the art would have been motivated to use polymers

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and/or colorants to stabilize ATP released from the disrupted living cells as adequately taught and/or suggested by US 5,017,564 for the expected benefits in stabilizing ATP for consecutive measurement and maximizing ATP amount correlation with the quantity of cells present in the analyzed samples.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

July 6, 2007



VERA AFREMOVA

PRIMARY EXAMINER